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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/657,749	05/30/96	METZ J	CGNE-101-2

18N2/1301

CALGENE INC
1920 FIFTH STREET
DAVIS CA 95616

EXAMINER	
BUI,F	
ART UNIT	**PAPER NUMBER**
1813	9

DATE MAILED: 10/01/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6/30/97.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-28 is/are pending in the application.

Of the above, claim(s) 1-17 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 18-28 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-28 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

★ U.S. GPO: 1996-410-238/40050

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to a method for the production of a very long chain fatty acid molecule, classified in class 800, subclass 205.

II. Claims 14-16, drawn to a method for decreasing the proportion of VLCFA in a plant, classified in class 536, subclass 24.5.

III. Claims 18-28, drawn to a DNA construct, classified in class 435, subclass 69.1.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I-II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The method to produce long chain fatty acid molecules and the method to decrease long chain fatty acid molecules are two distinct functions, and employ two distinct DNA molecules, namely a "very long chain fatty acid molecule-altering DNA sequence" and a "beta-ketoacyl-CoA-decreasing DNA sequence." Furthermore, the process of Group II employs antisense technology not required by the process of Group I.

3. Inventions I-II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA construct can also be used to express the proteins *in vitro*.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and fields of search, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Carl Schwedler on September 19, 1997, a provisional election was made with traverse to prosecute the invention of Group III, claims 18-28. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

7. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 18-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 9 of U.S. Patent No. 5445947. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed DNA construct of the instant application, comprising a gene encoding a condensing enzyme under the control of a seed-specific promoter, appears to be the same as the claimed DNA construct of US Pat. No. 5445947. It would appear that the sequences of US Pat. No. 5445947 could also be prepared from the primers as listed in claims 18 and 19 of the instant application.

9. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

10. Claims 18-19 are objected to because of the following informalities: the oligonucleotide primers should be identified by SEQ ID NOs, as required by 37 CFR 1.821(d). Appropriate correction is required.

11. Claims 18-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18-19, 22, 25-28 and dependents are indefinite because it is unclear which

enzymes are "condensing enzymes" and which are not. It is further unclear what the enzyme is condensing. Claims 18 and dependents are indefinite because of the phrase "naturally associated", because it is unclear which associations are "natural", which are "unnatural", and what association is being referred to. Is "association" synonymous with being in the same vicinity or does it have to be physically linked to the condensing enzyme? Furthermore, the length of the "heterologous DNA sequence" is unclear and could be as little as a single nucleotide. In claims 18 and dependents, it is unclear how long the chain of fatty acid molecule is by the phrase "very long chain", and how "very long" is different from "long" in terms of the number of carbons. It is also unclear how "degenerate" is defined, and which region(s) is considered "degenerate". In claim 21, it is unclear how "preferential expression" differs from "expression", and what level of expression would be considered as "preferential expression". In claims 23-24, it is unclear which enzymes are CE15 class and which are CE20 class of condensing enzymes, since they are not listed in the specification. Clarification and/or correction are required. New matter should be avoided.

12. Claims 18-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA sequences encoding wax synthase and fatty acyl reductase, does not reasonably provide enablement for all condensing enzymes and all heterologous DNA sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The specification teaches the utilization of wax synthase nucleic acid sequences in

conjunction with fatty acyl reductase proteins for production of wax esters in host cells (p. 3, last paragraph). It is unclear how other DNA constructs as encompassed by the claims would result in the production of wax esters, since it is not known what other protein combinations would result in the desired product. Would all heterologous DNA sequences yield the desired product when combined with DNA sequences encoding any condensing enzyme? Furthermore, since these primers do not have to be used together or in any particular combination, these primers would also hybridize with DNA sequences which would not have a heterologous DNA sequence, e.g., the DNA sequence of wax synthase without the fatty acyl reductase DNA sequence. Additionally, since the specification discloses hybridization under less stringent conditions which would allow for hybridization of sequences with as little as 50% sequence identity between the target sequence and the given sequence (p. 14-15), it is unclear how the wax synthase gene can be isolated at all. Further, since it is unclear which enzymes are condensing enzymes, it is unclear how one of ordinary skill can isolate the desired condensing enzyme using these primers. Without further guidance to these issues, a skilled artisan cannot practice the invention commensurate in scope with the claims without excessive burden and undue experimentation.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> > (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 18-21 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kridl et al. (US Pat. No. 5420034 (B)), Knauf et al. (US Pat. No. 5510255 (C)), or Jorgensen et al. (US Pat. No. 5231020 (D)). Kridl teaches expression constructs for transformation into plant cells to evaluate their ability to function with a heterologous structural gene and the seed-specificity, particularly for modifying fatty acid production in seed tissue of *Brassica* species using genes such as beta-ketoacyl-ACP synthases I and II (Abstract and col.6, l. 39-62). Likewise, Knauf teaches nucleic acid sequences encoding plant fatty acid synthases to modulate the amount of synthase present in plant host cells (col. 4, l. 40-51), as well as recombinant constructs containing a nucleic acid sequence encoding a synthase and a heterologous nucleic acid sequence (col. 6, l. 17-24). Similarly, Jorgensen teaches methods for producing plants exhibiting one or more desired phenotypic traits, comprising a DNA segment operably linked to a promoter, wherein said DNA segment is a gene encoding an enzyme of interest such as beta-ketoacyl ACP-synthetase (Abstract and col. 5, l. 43-55). Jorgensen further teaches the fusing of multiple sequences together to coordinately repress various different genes (col. 8, l. 15-37). Even though these references do not teach the primers of claims 18 and 19 of the instant application, it would appear that these nucleic acid constructs can be isolated using the

disclosed primers, especially under the low stringency conditions as stated in the specification. Absent of evidence to the contrary, the prior art anticipated or is an obvious variant of Applicant's claimed invention.

16. Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable in view of Kridl et al. (US Pat. No. 5420034 (B)), Knauf et al. (US Pat. No. 5510255 (C)), or Jorgensen et al. (US Pat. No. 5231020 (D)). The teachings of Kridl, Knauf, or Jorgensen have been discussed *supra*. It would appear that the primers disclosed in claims 18 and 19 of the instant application would also be capable of isolating the genes encoding the condensing enzymes from the genome of other plant species, such as those disclosed in claims 22-28, especially in view of the low stringency conditions as stated in the specification. Absent of evidence to the contrary, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to isolate the gene of interest for modification of protein expression in host cells with a reasonable expectation of success.

17. Papers relating to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 located in Crystal Mall 1. The Fax number for Art Unit 1813 is (703)308-4242. All Group 1800 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phuong Bui whose telephone number is (703)305-1996. The Examiner can normally be reached on Monday-Friday from 7 AM-4:30 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Don Adams, can be reached at (703)308-0570.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Phuong Bui
Patent Examiner
Group Art Unit 1813
September 29, 1997

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180